

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Claims 1-111 (canceled)

112 (New): A method of inducing an immune response to at least one antigen comprising

- (a) hydrating skin of an organism; and,
- (b) applying a formulation to the hydrated skin,
wherein the formulation comprises

- (i) at least one antigen which is derived from a pathogen and
- (ii) at least one adjuvant,

wherein an effective amount of the at least one antigen which is not encapsulated by liposomes induces the immune response in the organism.

113 (New): The method of claim 112, wherein the formulation consists essentially of antigen and adjuvant.

114 (New): The method of claim 112, wherein the formulation further comprises liposomes.

115 (New): The method of claim 112, wherein the pathogen is selected from the group consisting of bacterium, virus, fungus and parasite.

116 (New): The method of claim 112, wherein the antigen is selected from the group consisting of carbohydrate, glycolipid, glycoprotein, lipid, lipoprotein, phospholipid, and polypeptide.

117 (New): The method of claim 112, wherein the pathogen is a live or an attenuated live virus

RECEIVED

DEC 08 2003

TECH CENTER 1600/2900

and the antigen is expressed by the live or attenuated live virus.

118 (New): The method of claim 115, wherein the bacteria is anthrax.

119 (New): The method of claim 115, wherein the virus is rabies.

120 (New): The method of claim 112, wherein the adjuvant is selected from the group consisting of bacterial DNA, cytokines, chemokines, tumor necrosis factor alpha and lipopolysaccharides.

121 (New): The method of claim 112, wherein at least one adjuvant is an ADP-ribosylating exotoxin or toxoid thereof having adjuvant activity.

122 (New): The method of claim 121, wherein the ADP-ribosylating exotoxin or toxoid thereof is selected from the group consisting of pertussis toxin, a pertussis toxin toxoid having adjuvant activity, cholera toxin (CT), a CT toxoid having adjuvant activity, an *E. coli* heat-labile enterotoxin (LT), an LT toxoid having adjuvant activity, diphtheria toxin (DT), a DT toxoid having adjuvant activity, Pseudomonas exotoxin A, and, a Pseudomonas exotoxin A toxoid having adjuvant activity.

123 (New): The method of claim 112, wherein the formulation comprises an ADP-ribosylating exotoxin B subunit.

124 (New): The method of claim 112, wherein the formulation comprises an ADP-ribosylating exotoxin toxoid which is less toxic but remains immunogenic.

125 (New): The method of claim 112, wherein the formulation comprises an adjuvant selected from the group consisting of an ADP-ribosylating exotoxin in which ADP-ribosyl transferase

activity is inactivated; an ADP-ribosylating exotoxin chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein; an ADP-ribosylating exotoxin subunit chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein; and, an ADP-ribosylating toxoid chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein.

126 (New): The method of claim 112, wherein the formulation is a cream or gel or emulsion or ointment or lotion or paste or solution or suspension.

127 (New): The method of claim 112, wherein the formulation is applied to intact skin covering more than one draining lymph node field.

128 (New): The method of claim 112, further comprising applying alcohol to the intact skin prior to application of the formulation.

129 (New): The method of claim 112, wherein the formulation is applied with a patch.

130 (New): The method of claim 112, wherein the formulation further comprises a dressing.

131 (New): The method of claim 130, wherein the dressing is occlusive or non-occlusive.

132 (New): A method of inducing an immune response to at least one antigen comprising applying a formulation to skin of an organism, the formulation comprising

- (i) at least one antigen derived from a pathogen; and,
- (ii) at least one adjuvant;

wherein the formulation is selected from the group consisting of a solution, a cream, a gel, an emulsion, an ointment, a lotion, a paste, a suspension and combinations thereof;

wherein application of the formulation hydrates the skin; and, wherein an effective amount of the at least one antigen induces the immune response to the at least one antigen in the

organism.

133 (New): The method of claim 132, wherein the formulation is applied by patch.